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ATTACHMENT 8 (Amended 10/17/95)

Summary of Safety and Effectiveness

510(k) SUMMARY

US MEDICAL PRODUCTS, INC.
CONSENSUS® PCL SUBSTITUTING TIBIAL INSERT

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Date of Preparation: 17 Oct 1995

Trade Name: Consensus® PCL Substituting Tibial Insert

Common Name: posterior cruciate ligament substituting tibial insert knee prosthesis

Classification Name: Prosthesis, knee, patello/femorotibial, semi-constrained, cemented, polymer/metal/polymer, under classification 21CFR888.3560.

Substantial Equivalence: equivalent PCL Substituting Tibial Insert component:

Intermedics Orthopedics, Inc. Natural Knee® Ultracongruent Tibial Insert
K912663 SE 09-16-91

Device Description: The Consensus® Knee PCL Substituting Tibial Insert component is manufactured from ultra-high molecular weight polyethylene (ASTM F648). It is an asymmetric cruciate-retaining tibial component and is designed to articulate with the Consensus® Knee primary femoral component. Therefore, it has articulating surface geometry similar to the Consensus® Knee congruent tibial insert component. The inferior surface of each component employs dovetail grooves for positive interlocking with the tibial baseplate. The design is available in three sizes and each size is available in five thicknesses. The Consensus® PCL Substituting Tibial Insert will be provided sterile.

The Consensus® PCL Substituting Tibial Insert is designed for use with the following Consensus® Total Knee System components:

Consensus® Nonporous CoCr Femoral component
Consensus® Porous CoCr Femoral Component
Consensus® All Poly Patellar component
Consensus® Metal Back Patellar component
Consensus® Porous Titanium Stemmed Tibial Baseplate
Consensus® Nonporous Titanium Stemmed Tibial Baseplate
Consensus® CoCr Stemmed Tibial Baseplate

Intended Use: The Consensus® PCL Substituting Tibial Insert is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
2. Failed osteotomy or unicompartamental replacements
3. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

Summary of Technological Characteristics: The Consensus® PCL Substituting Tibial Insert is an asymmetric UHMWPE cruciate-substituting tibial component designed to articulate with the Consensus® Knee primary femoral component. The inferior surface of each component employs dovetail grooves for positive interlocking with the tibial baseplate. The design is available in three sizes and each size is available in five thicknesses.

Performance Data: The device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Consensus® PCL Substituting Tibial Insert is substantially equivalent to the predicate device.

Other Necessary Information: None Required